Decision Memo for Mobility Assistive Equipment (CAG-00274N)

Decision Summary

The Centers for Medicare and Medicaid Services (CMS) has determined the following:

CMS finds that the evidence is adequate to determine that mobility assistive equipment (MAE) is reasonable and necessary for beneficiaries who have a personal mobility deficit sufficient to impair their participation in mobility-related activities of daily living such as toileting, feeding, dressing, grooming, and bathing in customary locations in the home. Determination of the presence of a mobility deficit will use an algorithmic process, as outlined in Appendix A: Clinical Criteria for MAE Coverage, to provide the appropriate MAE to correct the mobility deficit.

Therefore, with this decision, CMS will modify the Medicare National Coverage Determination Manual and replace the coverage indications for canes (section 280.1), crutches (section 280.1), mobile geriatric chairs (section 280.1), motorized wheelchairs (section 280.1), quad-canes (section 280.1), rolling chairs (section 280.1), safety rollers (section 280.5), walkers (section 280.1), manual wheelchairs (section 280.1), power operated wheelchairs (section 280.1), specially sized wheelchairs (section 280.3), power operated vehicles (section 280.9) with the clinical conditions for MAE coverage specified in the newly revised section 280.3. For rolling chairs, CMS will maintain the coverage limitations on caster size.

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Decision Memo

To: Administrative File: CAG-00274N
Mobility Assistive Equipment (MAE)

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Subject: Coverage Decision Memorandum for Mobility Assistive Equipment (canes, crutches, walkers, manual wheelchairs, power wheelchairs, scooters)

Date: May 5, 2005

I. Decision

The Centers for Medicare and Medicaid Services (CMS) has determined the following:

CMS finds that the evidence is adequate to determine that mobility assistive equipment (MAE) is reasonable and necessary for beneficiaries who have a personal mobility deficit sufficient to impair their participation in mobility-related activities of daily living such as toileting, feeding, dressing, grooming, and bathing in customary locations in the home. Determination of the presence of a mobility deficit will use an algorithmic process, as outlined in Appendix A: Clinical Criteria for MAE Coverage, to provide the appropriate MAE to correct the mobility deficit.

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II. Background

Impaired mobility, combined with difficulty in performing mobility-related activities of daily living (MRADLs) such as toileting, feeding, dressing, grooming, and bathing, places the elderly at risk for a multitude of physiological and psychological consequences that can negatively affect health, well-being, and quality of life. These consequences include deep venous thrombosis, osteoporosis, under-nutrition, protein-energy malnutrition, and poor hygiene. Furthermore, compared to adults with met MRADL needs, people with MRADL assistance deficits are more likely to be in poor health (Kennedy 2001).

The use of assistive technology to aid ambulation goes back into prehistoric times when the simplest crutches and canes to compensate for functional disabilities were fashioned from sticks. Since then, the evolution of mobility assistance equipment has become increasingly more technological - from King Phillip II of Spain's rolling chair with foot rests in 1595 to the paraplegic watchmaker Stephen Farfler's self propelled chair which he built for himself in 1655 at the age of 22 to the specialized power wheelchairs of today.

Medicare beneficiaries may require mobility assistance for a variety of reasons and for varying durations because the etiology of the disability may be due to a congenital cause, injury, or disease. Thus, some beneficiaries experiencing temporary disability may need mobility assistance on a short-term basis while in contrast those living with chronic conditions or enduring disabilities will require mobility assistance on a permanent basis.

Medicare beneficiaries who depend upon mobility assistance are found in varied living situations. Some may live alone and independently while others may live with a caregiver or in a custodial facility. The beneficiary's environment is relevant to the determination of the appropriate form of mobility assistance that should be employed. For many beneficiaries, a device of some sort is compensation for the mobility deficit. Many beneficiaries experience co-morbid conditions that can impact their ability to safely utilize MAE independently or to successfully regain independent function even with mobility assistance.

The functional limitation as experienced by a beneficiary depends on the beneficiary's physical and psychological function, the availability of other support, and the beneficiary's living environment. A few examples include muscular spasticity, cognitive deficits, the availability of a caregiver, and the physical layout, surfaces, and obstacles that exist in the beneficiary's living environment. Thus, two beneficiaries with the same physical disease diagnosis may experience vastly disparate functional limitations on a day-to-day basis.

III. History of Medicare Coverage

Medicare is a defined benefit program. An item or service must fall within one or more benefit categories, and not otherwise be excluded by statute from coverage §1812 (scope of Part A); §1832(scope of Part B); §1861(s)(definition of medical and other services). Section 1861(n) of the Social Security Act lists items that are included as durable medical equipment (DME), including wheelchairs.

CMS has several national coverage determinations (NCD) regarding various mobility assistive equipment. Section 280.1 of the Medicare NCD manual lists items categorized as Durable Medical Equipment, including wheelchairs, canes, crutches, rolling chairs and safety rollers Section 280.3 addresses specially sized wheelchairs and section 280.5 focuses on safety rollers (walkers). Furthermore, section 280.9 addresses power operated vehicles that may be used as wheelchairs.

On December 15, 2004, CMS opened an NCD on mobility assistive equipment to examine and set the clinical criteria for the provision of this equipment.

Recent allegations of wheelchair fraud and abuse have focused considerable public interest on the provision of wheelchairs under the Medicare benefit. The agency has responded with a multifaceted plan to ensure the appropriate prescription of wheelchairs to beneficiaries who need them. One facet of this plan is the delineation of suggested clinical conditions of wheelchair coverage. CMS solicited public comment through a number of open door forums and other methods. Many advocacy groups have suggested that the agency adopt a function-based interpretation of its historical "bed or chair confined" criterion for wheelchair coverage.

Historically, wheelchairs have been "covered if [the] patient's condition is such that without the use of a wheelchair he would otherwise be bed or chair confined. An individual may qualify for a wheelchair and still be considered bed confined. Wheelchairs (power operated) and wheelchairs with other special features are covered if [the] patient's condition is such that a wheelchair is medically necessary and the patient is unable to operate the wheelchair manually."[1] The Durable Medical Equipment Regional Carriers (DMERCs) have used this standard to process wheelchair claims.

In June of 2004, CMS formed a workgroup (the Interagency Wheelchair Work Group-IWWG) of Federal employees to review its current policy for wheelchair provision and to analyze the published scientific literature on the use of wheelchairs. The IWWG was assembled to comprise clinicians, including physicians, occupational therapists, and physical therapists, researchers, and policy specialists who have practical experience with mobility equipment utilization issues from different federal agencies including the Veterans Administration (VA), National Institutes of Health (NIH), Food and Drug Administration (FDA), Department of Education (ED), as well as different areas within CMS, including the Office of Clinical Standards and Quality (OCSQ), Center for Medicare Management (CMM), Office of Financial Management (OFM), Office of External Affairs (OEA), and Center for Medicaid and State Operations (CMSO).

The IWWG made several recommendations for the clinical interpretation of CMS' statutory, regulatory and clinical guidelines, including the adoption of a function-based determination of medical necessity. A function-based determination might consider the beneficiary's inability to safely accomplish activities of daily living, such as toileting, feeding, dressing, grooming, and bathing with and without the use of mobility equipment, such as a wheelchair. CMS decided that the recommendations of the IWWG are best reviewed with the benefits of public participation which are available through the NCD process. Accordingly, on December 15, 2004, CMS initiated the national coverage determination to address the appropriate prescription of Mobility Assistive Equipment.

Consistent with IWWG recommendations and our internal review, CMS chose to use activities of daily living such as toileting, feeding, dressing, grooming, and bathing as these are activities necessary to serve a medical purpose in the home. We collectively named these mobility related activities of daily living (MRADLs). Medicare is a defined benefit program. MAE is covered under the benefit category of DME. DME is defined as equipment that 1) can withstand repeated use, 2) is primarily and customarily used to serve a medical purpose, 3) generally is not useful to an individual in the absence of an illness or injury, and 4) is appropriate for use in the home (42 C.F.R. § 414.202). Instrumental activities of daily living (IADLs) were not used in determining coverage since they are not limited to describing mobility functions in the home for a medical purpose, as defined by 42 C.F.R. § 414.202

IV. Timeline of Recent Activities

12/15/04	CMS internally generated the Mobility Assistive Equipment NCD and posted the tracking sheet along with the IWWG document.
1/14/05	The 30-day public comment period closed on this date.
2/3/05	CMS posted the proposed decision memo online at http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=143
	The second public comment period began on this date.
2/24/05	CMS convened a Special Open Door Forum on the Medicare Wheelchair benefit.
3/7/05	The second public comment period closed on this date

V. FDA Status

The FDA states the following specifically:[2]

The Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act established three regulatory classes for medical devices. The three classes are based on the degree of control necessary to assure the various types of devices are safe and effective.

Class I *– These devices present minimal potential for harm to the user and are often simpler in design than Class II or Class III devices. Examples include enema kits and elastic bandages. Forty-seven percent of medical devices fall under this category and 95% of these are exempt from the regulatory process.*

Class II *– Most medical devices are considered Class II devices. Examples of Class II devices include powered wheelchairs and some pregnancy test kits. Forty-three percent of medical devices fall under this category.*

Class III *– These devices usually sustain or support life, are implanted, or present potential unreasonable risk of illness or injury. Examples of Class III devices include implantable pacemakers and breast implants. Ten percent of medical devices fall under this category.*

Furthermore, items of mobility assistive equipment are specifically categorized in the FDA Code of Federal Regulations (CFR) as follows:[3]

21CFR § 890.3860 Mechanical wheelchair. (a) Identification: *A mechanical wheelchair is a manually operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position.*
(b) Classification: *Class I (general controls).*
21CFR § 890.3890 Powered wheelchair.
(a) Identification: A powered wheelchair is a battery-operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position.
(b) Classification: *Class II (performance standards).*
21CFR § 890.3790 Cane. (a) Identification: *A cane is a device intended for medical purposes that is used to provide minimal weight support while walking. Examples of canes include the following: A standard cane, a forearm cane, and a cane with a tripod, quad, or retractable stud on the ground end.*
(b) Classification: *Class I (general controls).*
21CFR § 890.3790 Cane, crutch, and walker tips and pads. (a) Identification: *Cane, crutch, and walker tips and pads are rubber (or rubber substitute) device accessories intended for medical purposes that are applied to the ground end of mobility aids to prevent skidding or that are applied to the body contact area of the device for comfort or as an aid in using an ambulatory assist device.*
(b) Classification: *Class I (general controls).*
21CFR § 890.3910 Wheelchair accessory. (a) Identification: *A wheelchair accessory is a device intended for medical purposes that is sold separately from a wheelchair and is intended to meet the specific needs of a patient who uses a wheelchair. Examples of wheelchair accessories include but are not limited to the following: armboard, lapboard, pusher cuff, crutch and cane holder, overhead suspension sling, head and trunk support, and blanket and leg rest strap.*
(b) Classification: *Class I (general controls).*

VI. General Methodological Principles

When making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (§1862(a)(1)(A) of the Social Security Act.) The critical appraisal of the evidence enables us to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve net health outcomes for Medicare beneficiaries. The general methodological principles of study design utilized in our review of the evidence are in Appendix B.

VII. Evidence

A. Introduction:

When making national coverage determinations, CMS evaluates relevant clinical research studies to determine whether or not the evidence is of sufficient strength to support a finding that an item or service is reasonable and necessary. Methodologists have developed criteria to determine weaknesses and strengths of clinical research. Some of the methodological attributes of individual studies associated with stronger evidence are summarized in Appendix B.

B. Discussion of evidence reviewed

1. Assessment Questions

The development of an assessment in support of Medicare coverage decisions is based on the same general question for almost all requests: "Is the evidence sufficient to conclude that the application of the technology under study will improve final health outcomes for Medicare patients?"

The formulation of specific questions for the assessment recognizes that the effect of an intervention can depend substantially on how it is delivered, to whom it is applied, the alternatives with which it is being compared, and the setting where it is used. In order to appraise the net health outcomes of using MAE, CMS sought to address the following question:

Is the quality of evidence adequate to determine that the use of mobility assistive equipment enables a Medicare beneficiary to participate in mobility-related activities of daily living?

2. Internal Technology Assessment

Search Strategy:
PubMed and CINAHL were used to search for relevant documents. Our searches identified over 700 documents. Inclusion criteria were as follows:

- Studies that addressed the use of MAE, including wheelchairs, by individuals who are unable to adequately participate in mobility-related activities of daily living (despite the use of other assistive equipment) in domestic environments were included.
- Clinical studies were included regardless of design, except for case reports, which were excluded.
- English language only.
- Studies of any type of wheelchair (manual wheelchairs, powered wheelchairs, and scooters) were included.

Ten studies addressed the effect of MAE (including wheelchairs) on ability to participate in MRADLs. One of the studies was a randomized controlled trial, one was a prospective cohort study, and the rest were retrospective analyses of cross-sectional surveys. The results of each of these studies are summarized in Appendix C: Evidence Tables

In general, the term MAE was defined quite broadly to include any items and techniques that eliminate, ameliorate, or compensate for functional limitations (Agree 2000). As such, MAE included, but was not limited to canes, crutches, walkers, rolling chairs, wheelchairs and crutches when specified.

Authors found that even with the use of assistive equipment, individuals reported difficulty participating in MRADLs (Taylor 2004). However, persons using assistive equipment tended to have higher MRADL function when using the equipment when compared to people not using a MAE (Hammel 2002). There was also a strong and consistent relationship between the use of a MAE, including wheelchairs, and requiring fewer hours of personal assistance to perform MRADLs (Hoenig 2003).

Persons relying on MAE, including wheelchairs, reported less residual disability than those relying on personal assistance (Agree 2000 and Verbrugge 1997) and MAE users reported less unmet need for personal care (Agree 2003). An RCT found that, though there is decline in function in both people who use MAE, including wheelchairs, and those who do not, over time, the MAE group has less of a decline (Mann 1999).

Overall, individuals using assistive equipment had lower MRADL function without the equipment than individuals who did not use assistive equipment (Hammel 2002). Individuals who used wheelchairs had lower MRADL function without the wheelchairs than individuals using other mobility aids (Allen 2001), and wheelchair users required more personal assistance than did users of other mobility aids (Agree 2000).

4. MCAC

The Medicare Coverage Advisory Committee was not convened for this NCD.

5. Evidence-based guidelines

A search for published evidenced-based guidelines on the appropriate prescription of mobility assistive equipment, including canes, crutches, walkers, rolling chairs, wheelchairs and scooters, was conducted. No evidenced-based guidelines were identified.

6. Professional Society Position Statements

A search for published professional society position statements on the appropriate prescription of mobility assistive equipment, including canes, crutches, walkers, rolling chairs, wheelchairs and scooters, was conducted. No professional society position statements were identified.

7. Expert Opinion

The IWWG reviewed current CMS policy for wheelchair provision and analyzed the published scientific literature on the use of wheelchairs. The IWWG made several recommendations for the clinical interpretation of CMS' statutory, regulatory and clinical guidelines, including the adoption of a function-based determination of medical necessity. A function-based determination would consider the beneficiary's inability to safely accomplish mobility-related activities of daily living, such as toileting, grooming, and eating with and without the use of mobility equipment, such as a wheelchair.

As part of the IWWG report, the group proposed guidelines for the provider regarding the appropriate prescription of MAE and the clinical criteria for their appropriate use. The IWWG envisioned the prescriber following the clinical criteria schema (detailed in the following sections) to ensure the beneficiary received the most appropriate equipment. The following sections are based on the IWWG guidelines.

Appropriate Prescription of Mobility Equipment

An assessment of the beneficiary's physical, cognitive, and emotional limitations and abilities, willingness to use mobility assistive equipment on a routine basis, and the beneficiary's typical home environment is recommended to determine the appropriate prescription of mobility equipment. In order to facilitate the application of the new functional criteria, the IWWG proposed the following suggestions for the provision of wheelchairs.

Provision of Mobility Assistive Equipment Under Medicare Should Include All Five Points Below

- The beneficiary's physical limitations (diminished strength, speed, endurance, range of motion, coordination, sensation, deformity) prevent the beneficiary from accomplishing mobility-related activities of daily living in the home.

- The beneficiary's mental capabilities (cognition, orientation, communication, judgment, memory, comprehension, affect, and suitable behavior) are sufficient for safe and adequate performance of mobility -related activities of daily living with the use of mobility assistive equipment.
- The beneficiary's physical capabilities (strength, speed, endurance, range of motion, coordination, sensation) are sufficient for safe and adequate performance of mobility-related activities of daily living with the use of a mobility assistive equipment.
- The characteristics of the beneficiary's typical home environment in which the activities of daily living are encountered (surfaces, presence or absence of surface accommodations, obstacles, accessibility, changes in grade, and distances covered) are suitable for use of the appropriate equipment.
- The beneficiary demonstrates willingness to use the equipment routinely.

Clinical Criteria for Wheelchair Prescribing

The beneficiary, the beneficiary's family or other caregiver, or a clinician will usually initiate the discussion and consideration of wheelchair use. Sequential consideration of the questions below provides clinical guidance for the prescription of a device of appropriate type and complexity to restore the beneficiary's ability to perform mobility-related activities of daily living. These questions correspond to the numbered decision points on the accompanying flow chart.

1. Does the beneficiary have a mobility limitation causing an inability to perform one or more mobility-related activities of daily living in the home? A mobility limitation is one that
    a. Prevents the beneficiary from accomplishing the mobility-related activities of daily living entirely, or
    b. Places the beneficiary at reasonably determined heightened risk of morbidity or mortality secondary to the attempts to perform mobility-related activities of daily living, or
    c. Prevents the beneficiary from completing the mobility-related activities of daily living within a reasonable time frame.

2. Are there other conditions that limit the beneficiary's ability to perform mobility-related activities of daily living at home?
    a. Some examples are significant impairment of cognition or judgment and/or vision.
    b. For these beneficiaries, the provision of a wheelchair might not enable them to perform mobility-related activities of daily living if the comorbidity prevents effective use of the MAE or reasonable completion of the tasks even with a wheelchair.

3. If these other limitations exist, can they be ameliorated or compensated sufficiently such that the additional provision of a mobility equipment will be reasonably expected to materially improve the beneficiary's ability to perform mobility-related activities of daily living in the home?
    a. A caregiver, for example a family member, may be compensatory, if consistently available in the beneficiary's home and willing and able to safely operate and transfer the beneficiary to and from the wheelchair and to transport the beneficiary using the wheelchair.
    b. If the amelioration or compensation requires the beneficiary's compliance with treatment, for example medications or therapy, substantive non-compliance, whether willing or involuntary, can be grounds for denial of MAE coverage if it results in the beneficiary continuing to have a significant limitation. It may be determined that partial compliance results in adequate amelioration or compensation for the appropriate use of a mobility assistive equipment.

4. Does the beneficiary demonstrate the capability and the willingness to consistently operate the device safely?
    a. Safety considerations include personal risk to the beneficiary as well as risk to others. The determination of safety may need to occur several times during the process as the consideration focuses on a specific device.
    b. A history of unsafe behavior in other venues may be considered.

5. Can the functional mobility deficit be sufficiently resolved by the prescription of a cane or walker?

a. The cane or walker should be appropriately fitted to the beneficiary for this evaluation.
b. Assess the beneficiary's ability to safely use a cane or walker.

6. Does the beneficiary's typical environment support the use of wheelchairs or scooters/POVs?
   a. Determine whether the beneficiary's environment will support the use of these mobility assistive equipment.
   b. Keep in mind such factors as temperature, physical layout, surfaces, and obstacles, which may render an item of mobility assistive equipment unusable in the beneficiary's home.

7. Does the beneficiary have sufficient upper extremity function to propel a manual wheelchair in the home through the course of the performance of mobility-related activities of daily living during a typical day? The manual wheelchair should be optimally configured (seating options, wheelbase, device weight and other appropriate accessories) for this determination.
   a. Limitations of strength, endurance, range of motion, coordination and absence or deformity in one or both upper extremities are relevant.
   b. A beneficiary with sufficient upper extremity function may qualify for a manual wheelchair. The appropriate type of manual wheelchair, i.e. light weight, power assisted, etc. should be determined based on the beneficiary's physical characteristics and anticipated intensity of use.
   c. The beneficiary's home should provide adequate access, maneuvering space and surfaces for the operation of a manual wheelchair.
   d. Assess the beneficiary's ability to safely use a manual wheelchair.

8. Does the beneficiary have sufficient strength and postural stability to operate a power-operated vehicle (POV/scooter)?
   a. A POV is a 3 or 4-wheeled device with tiller steering and limited seat modification capabilities. The beneficiary must be able to maintain stability and position for adequate operation.
   b. The beneficiary's home should provide adequate access, maneuvering space and terrain for the operation of a POV.
   c. Assess the beneficiary's ability to safely use a POV/scooter.

9. Are the additional features provided by a power wheelchair needed to allow the beneficiary to perform one or more mobility-related activities of daily living?
   a. These devices are typically controlled by a joystick or alternative input device, and can accommodate a variety of seating needs.
   b. The beneficiary's home should provide adequate access, maneuvering space and terrain for the operation of a power wheelchair.
   c. Assess the beneficiary's ability to safely use a power wheelchair.

Figure 1: [PDF, 20KB]

8. Public Comments

In the initial public comment period after the tracking sheet for the MAE NCD was posted, CMS received 193 comments on the IWWG document that accompanied the tracking sheet. In light of the large number of public comments, we are grouping the comments under the various topics presented.

CMS received numerous comments supporting the transition from the past standard of "bed or chair confined" to the new functional criteria as recommended by the IWWG. Commenters observed that the policy of "bed or chair confined" impeded beneficiary independence, was confusing, and caused inconsistent interpretations by providers resulting in unwarranted denials of the benefit. CMS anticipates that the functional criteria will provide beneficiaries greater access to appropriate MAE and better address their individual needs.

Some commenters wrote that they were concerned the "appropriate technology" policy would limit beneficiary access to power wheelchairs and scooters. CMS's policy is to provide each beneficiary with the MAE that is most appropriate for the individual need. Safety and usability concerns must be accounted for in the provision of MAE in order to safeguard the welfare of our beneficiaries.

Some commenters asked CMS to extend the criteria to include activities conducted outside of the home environment. Medicare law lists certain items of durable medical equipment (DME) used in a patient's home for which Medicare payment may be made, including wheelchairs. The regulation, 42 C.F.R. § 414.202, further defines DME as equipment that 1) can withstand repeated use, 2) is primarily and customarily used to serve a medical purpose, 3) generally is not useful to an individual in the absence of an illness or injury, and 4) is appropriate for use in the home. An NCD would not be the appropriate mechanism to change that.

CMS received quite a few comments that revealed confusion over the "in the home" restriction. These commenters understood that the "in the home" restriction meant our beneficiaries were not allowed to use their wheelchairs outside of the home. CMS would like to reassure the community that the DME benefit category does not prevent beneficiaries from using their wheelchairs outside of the home. The "in the home" restriction means that for DME, such as a wheelchair, to be covered, a beneficiary must have a medical need to use the DME in the home. This requirement excludes DME from coverage if there is only a medical need to use the equipment outside of the home. However, if DME is determined to be medically necessary in the home, the equipment would still be covered and the beneficiary could use the equipment outside the home.

Some commenters expressed concern that wheelchairs would be denied if a beneficiary relied on a caregiver to compensate and operate the wheelchair for the beneficiary. For example, one commenter asserted that a quadriplegic beneficiary would not qualify for a wheelchair under the functional standard that CMS is proposing. The IWWG recommended and CMS concurs that the contributions of a caregiver may compensate to overcome the beneficiary's limitations to operate a wheelchair. For example, the feeding or grooming of the beneficiary by a caregiver is acceptable as a compensation for the beneficiary's inability to personally perform those activities. In addition, the IWWG recommended and CMS concurs that the determination of a beneficiary's functional limitation should be based on the beneficiary's independent function. We are clarifying that the presence of a caregiver who can lift and carry the beneficiary from room to room would not be used to classify the patient as functionally ambulatory.

Some commenters would like to see CMS require a patient evaluation conducted by an independent and qualified clinician. These comments are beyond the scope of this national coverage determination.

Other commenters requested an assessment for the continuum of mobility equipment. The decision supports a stepwise consideration of the sufficiency of mobility assistive equipment ranging from canes and walkers through manual and power wheelchairs.

In the second public comment period, CMS received 113 additional comments regarding the proposed decision memo. Many of these comments touched on themes that were presented in the first public comment period and which CMS has responded to in the above section.

Some commenters, while supporting the replacement of the "bed or chair confined" standard with function-based clinical criteria, indicated that function should not be tied to MRADLs. Alternatively, some suggested that MRADLs should be better defined to include instrumental activities of daily living (IADLs). As mentioned previously, the primary purpose of DME is to help patients function in the home, and our regulations require that this equipment be appropriate for use in the home (42 C.F.R. § 410.38(a)). We believe that the MRADL is the most appropriate recognized standard of activities for items furnished in this setting. Because the IADL focuses on activities that can be performed outside of the home, we believe that consideration of those broader activities would be inappropriate.

Many commenters showed support for ADLs and suggested that mobility, itself, be included as an ADL. Some beneficiaries with certain disabilities would not be able to perform ADLs on their own even with the provision of an MAE but need wheelchairs in order to be moved from one place to another. CMS has clarified the language to support coverage of MAE in order for beneficiaries to participate in (in this case, with the help of a caregiver) MRADLs in customary locations in the home. However, the purpose of mobility in these settings is to accomplish ADLs. Mobility is not included in the definition of MRADL because, by itself, it does not serve a medical purpose.

Some commenters discussed documentation issues extensively. While CMS does require adequate documentation to establish that coverage conditions are met, the complexity of the issues indicate this is best addressed in an initiative separate from the NCD.

In addition, the issues pertaining to who is qualified to do the patient evaluation and similar comments pertaining to § 302 of the Medicare Modernization Act is beyond the scope of this NCD.

Several commenters commended CMS for not setting the coverage conditions on diagnosis codes.

CMS received several comments discussing the need for multiple items of MAE concurrently. Local contractors may determine if the beneficiary's unique needs indicate the appropriate use of additional MAE.

One commenter wrote that non-compliance should not be a determinant of medical necessity or be the basis of a denial of coverage. CMS is committed to providing MAEs to beneficiaries who need them. If the beneficiary expresses that he or she does not need or will not use the MAE, then that is a legitimate reason to determine that an MAE is not warranted.

Some commenters suggested that CMS be more specific on environmental assessments and conditions. Due to the many differences in the environments of beneficiaries, CMS believes the environment must be assessed for each individual as specified in the conditions for coverage. CMS believes local contractors may craft policy for environment assessments as consistent with the conditions for coverage.

A commenter proposed that canes, crutches, and walkers should not be included in the scope of this NCD. CMS believes that because these devices, along with other mobility assistive equipment like scooters and manual and power wheelchairs, fall along a continuum of technology, any discussion which did not include the more basic technology devices would be incomplete.

Some commenters supported scooters/power-operated vehicles (POVs) as a lower cost alternative to power wheelchairs. CMS expects the beneficiary to be provided with the technology that most appropriately addresses the beneficiary’s needs as determined by the coverage criteria for the MAE benefit.

Finally, a commenter pointed out that the Medicare population under age 65, estimated at 6 million, may have mobility needs and functional activity levels which differ from more elderly beneficiaries. CMS acknowledges that our beneficiaries face a wide variety of mobility challenges due to many different causes and conditions and that this commenter has presented a legitimate concern. CMS has constructed the clinical algorithm for MAE Coverage with the individual beneficiary in mind so that the most appropriate MAE is provided to meet the needs of each beneficiary, whether he or she is above or below 65, or at a higher or lower level of function.

VIII. CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act § 1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." § 1862(a)(1)(A).

In this analysis, CMS has addressed numerous items that it has termed "mobility assistive equipment" and includes within that category canes, crutches, walkers, rolling chairs, manual wheelchairs, power wheelchairs, and scooters. This list is not exhaustive.

The potential for appropriate equipment to reduce use of personal assistance is apparent (Hoenig 2003). In addition, data suggest that people who do not use MAE to cope with disability report more dependence on others than those who use MAE (Hoenig 2003). Finally, many severely disabled people own no assistive equipment and substantial unmet needs are reported. Thus, CMS appreciates the necessity of MAE for Medicare beneficiaries or their caregivers who are capable of safely operating MAE to participate in MRADLs.

Using input from the IWWG as well as internal review, CMS chose to use activities of daily living such as toileting, feeding, dressing, grooming, and bathing as these are activities necessary to serve a medical purpose in the home. Medicare is a defined benefit program. MAE is covered under the benefit category of DME. DME is defined as equipment that 1) can withstand repeated use, 2) is primarily and customarily used to serve a medical purpose, 3) generally is not useful to an individual in the absence of an illness or injury, and 4) is appropriate for use in the home (42 C.F.R. § 414.202). Instrumental activities of daily living (IADLs) were not used in determining coverage since they are not limited to describing mobility functions in the home for a medical purpose, as defined by 42 C.F.R. § 414.202.

As stated in the evidence section, in general, authors found that even with the use of assistive equipment individuals reported difficulty in performing MRADLs. However, persons using assistive equipment tended to have higher MRADL function when using the equipment, and required fewer hours of personal assistance than when not using the equipment. Individuals using assistive equipment had lower MRADL function without the equipment than individuals who did not use assistive equipment. Individuals who used wheelchairs had lower MRADL function without the wheelchairs than individuals using other mobility aids.

The literature reviewed is (see Appendix C: Evidence Tables) of large sample size (109 - over 40,000) and includes Medicare aged beneficiaries, making the results generalizable to the Medicare population. Though most studies were retrospective in nature, the results were consistent suggesting that the quality of the literature is adequate to conclude that, for beneficiaries who have a mobility deficit sufficient to impair their performance of mobility-related activities of daily living**,** the use of a MAE, including a wheelchair, can be reasonable and necessary, under appropriate conditions, for a Medicare beneficiary to participate in MRADLs.

The published literature does not provide detailed guidance regarding which specific item of MAE is appropriate to permit a beneficiary with a specific mobility limitation to participate in specific mobility-related activity of daily living. This appears at least in part to be due to several factors. As we described earlier, mobility assistance equipment predates the modern scientific era, especially the relatively modern Evidence Based Medicine paradigm. Historically there has been little innovation in this area, and minimal impetus to undertake practical clinical trials in the face of other health priorities. Not unlike many other aspects of medical practice, the use of mobility assistance equipment has arisen from a base of collective clinical experience and inference of benefit. In this light we believe that the best available evidence is found largely in the expertise of impartial practitioners. Recognizing this, CMS has utilized the expertise of the IWWG outlined in section VII.7 in crafting our criteria for specific equipment.

CMS believes that an algorithmic process that sequentially considers the appropriate MAE that corrects the mobility deficit is the appropriate process to follow in covering MAEs. We believe that the Clinical Criteria for MAE Coverage, described in Appendix A, sufficiently describes this process. Utilizing such a process will ensure that the beneficiary (or caregiver) is able to maintain as much independence as physically and mentally possible, thereby ensuring the beneficiary's MRADLs are maintained.

As outlined in Appendix A: Clinical Criteria for MAE Coverage, a request is made by the beneficiary, caregiver or physician. After assessing the beneficiary's physical limitations, confirming that the beneficiary (or caregiver) has the mental and physical capabilities to operate the MAE, and confirming that the beneficiary is willing to use the MAE, the appropriate MAE is covered following the algorithm. This process represents a partnership between the beneficiary, caregiver and health care provider. As such, it allows for the most comprehensive assessment of the beneficiary's physical abilities and will provide the beneficiary with the most appropriate MAE.

IX. Conclusions:

The Centers for Medicare and Medicaid Services (CMS) has determined the following:

CMS finds that the evidence is adequate to determine that mobility assistive equipment (MAE) is reasonable and necessary for beneficiaries who have a personal mobility deficit sufficient to impair their participation in mobility-related activities of daily living such as toileting, feeding, dressing, grooming, and bathing in customary locations in the home. Determination of the presence of a mobility deficit will use an algorithmic process, as outlined in Appendix A: Clinical Criteria for MAE Coverage, to provide the appropriate MAE to correct the mobility deficit.

Therefore, with this decision, CMS will modify the Medicare National Coverage Determination Manual and replace the coverage indications for canes (section 280.1), crutches (section 280.1), mobile geriatric chairs (section 280.1), motorized wheelchairs (section 280.1), quad-canes (section 280.1), rolling chairs (section 280.1), safety rollers (section 280.5), walkers (section 280.1), manual wheelchairs (section 280.1), power operated wheelchairs (section 280.1), specially sized wheelchairs (section 280.3), and power operated vehicles (section 280.9) with the clinical conditions for MAE coverage specified in the newly revised section 280.3. For rolling chairs, CMS will maintain the coverage limitations on caster size.

Appendices A, B, & C [PDF, 132KB]

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[1]http://63.241.27.78/manuals/06_cim/ci60.asp#_1_8, accessed on 1/12/05

[2]http://www.fda.gov/cdrh/consumer/geninfo.html, accessed on 12/29/2004.

[3]http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=890.3850&SearchTerm=wheelchairs, accessed on 12/29/2004.

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Bibliography

Agree EM, Freedman VA. A comparison of assistive technology and personal care in alleviating disability and unmet need. Gerontologist 2003 Jun;43(3):335-44.

Agree EM, Freedman VA. Incorporating assistive devices into community-based long-term care: an analysis of the potential for substitution and supplementation. J Aging Health 2000 Aug;12(3):426-50.

Agree EM. The influence of personal care and assistive devices on the measurement of disability. Soc Sci Med 1999 Feb;48(4):427-43.

Allen SM, Foster A, Berg K. Receiving help at home: the interplay of human and technological assistance. JGerontol B Psychol Sci Soc Sci 2001 Nov;56(6):S374-82.

Hammel J, Lai JS, Heller T. The impact of assistive technology and environmental interventions on function and living situation status with people who are ageing with developmental disabilities. Disabil Rehabil 2002 Jan;24(1-3):93-105.

Hoenig H, Taylor DH Jr, Sloan FA. Does assistive technology substitute for personal assistance among the disabled elderly. Am J Public Health 2003 Feb;93(2):330-7.

Kennedy J. Unmet and undermet need for activities of daily living and instrumental activities of daily living assistance among adults with disabilities Med Care. 2001 Dec;39(12):1305-12

Mann WC, Ottenbacher KJ, Fraas L, Tomita M, Granger CV. Effectiveness of assistive technology and environmental interventions in maintaining independence and reducing home care costs for the frail elderly. A randomized controlled trial. Arch Fam Med 1999 May-Jun;8(3):210-7.

Taylor DH, Hoenig H. The effect of equipment usage and residual task difficulty on use of personal assistance, days in bed, and nursing home placement. J Am Geriatr Soc 2004 Jan;52(1):72-9.

Verbrugge LM, Rennert C, Madans JH. The great efficacy of personal and equipment assistance in reducing disability. Am J Public Health 1997 Mar;87(3):384-92.

Verbrugge LM, Sevak P. Use, type, and efficacy of assistance for disability. J Gerontol B Psychol Sci Soc Sci 2002 Nov;57(6):S366-79.

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